

### **REMARKS**

Claims 10-15 are currently pending in this application after entry of the present amendment. Claims 1 to 9 have been cancelled. The Office Action dated March 25, 2005 indicated that claims 10-15 were rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. Claim 14 was also rejected under 35 U.S.C. §112, first paragraph, for lack of written description. The Office Action also indicated that claims 10-15 were rejected under the judicially created doctrine of obviousness-type double patenting.

Claim 10 has been amended to recite a DNA expression vector comprising a DNA sequence encoding a biologically active recombinant NH<sub>2</sub>-terminal polypeptide fragment of bactericidal/permeability-increasing protein, wherein the bactericidal/permeability-increasing protein has the amino acid sequence set forth in Figure 5. Claim 10 also recites that the fragment is up to about half the size of said protein, in the proper reading frame. The amendment is supported throughout the specification including, for example, at page 5, lines 31-34, page 12, lines 15-23, and Figure 5.

### **The Status of the Parent Application Has Been Updated**

The Office Action dated March 25, 2005 stated that the status of all U.S. Application 09/866,514 needed to be updated to reflect that the application is now a U.S. patent. Applicants have amended the specification to indicate that the application has issued as U.S. Patent No. 6,652,862.

**The Brief Description Of The Drawings Has Been Updated**

The Office Action stated that the Brief Description of the Drawings on page 5 of the specification had to be updated to correctly reflect the figures in the drawings. The Office Action indicated that the Figures should refer to Figures 2a and 2b, Figures 3A-3D, and Figures 5A-5D. Applicants have amended the Brief Description of the Drawings so that it refers to Figures 2a and 2b, Figures 3A-3D, and Figures 5A-5D.

**The Title Has Been Amended To Be More Descriptive**

The Office Action stated that the title of the invention was not descriptive, and a new title was required that was clearly indicative of the invention. The Office Action suggested the title, "DNA encoding bactericidal/permeability increasing proteins." Applicants have amended the title accordingly.

**Response To The Rejection For Indefiniteness**

The Office Action dated March 25, 2005 rejected claims 10-15 under 35 U.S.C. §112, second paragraph, for indefiniteness. The Office Action stated that claim 10 was vague and indefinite because the mere recitation of a name was not sufficient. The Office Action also stated that the name "bactericidal/permeability-increasing protein" is used for other proteins/protein fragments in the prior art, e.g., rabbit BPI. The Office Action stated that the claim must provide any structural properties, such as the nucleic acid sequence or the amino acid sequence of the protein which the DNA encodes, which would allow for one to identify the nucleic acid sequence without ambiguity. The Office Action also stated that the actual sequence of the DNA is a critical limitation.

Applicants submit that it is not necessary to recite the DNA sequence and that

the DNA sequence is not a "critical limitation" as indicated by the Office Action. However, in order to expedite the allowance and issuance of the present application, claim 10 has been amended to recite a DNA sequence encoding a biologically active recombinant NH<sub>2</sub>-terminal polypeptide fragment of bactericidal/permeability-increasing protein wherein the bactericidal/permeability-increasing protein has the amino acid sequence set forth in Figure 5. Figure 5 sets forth the amino acid sequence of human bactericidal/permeability-increasing protein. Figure 5 also sets forth a corresponding amino acid sequence for human BPI.

The Office Action also stated that claim 13 was vague and confusing because it was unclear if the sequence recited in the claim represents the entire NH<sub>2</sub> -terminal polypeptide fragment encoded by the DNA expression vector of claim 10, or if it is just a partial fragment of the larger sequence.

Applicants submit that claim 13 covers NH<sub>2</sub>-terminal fragments up to about half the size of human BPI. Similar claim language is found in U.S. Patent Nos. 5,948,408; 5,980,897; and 6,132,775.

Applicants submit that the rejection of claims 10-15 for indefiniteness may properly be withdrawn.

#### **Response To The Rejection For Lack Of Written Description**

The Office Action dated March 25, 2005 rejected claims 14 under 35 U.S.C. §112, first paragraph, for lack of written description. The Office Action stated that claim 14 recited that the vector encodes an amino acid sequence from residue 1 to about amino acid residue 220 as set out in Figure 5. The Office Action stated that support for this limitation could not be found.

Applicants submit that the subject matter of claim 14 is supported and described throughout the specification including, for example, at page 12, lines 15 to 20, which states:

The sequence information contained in FIG. 5 can be employed to synthesize the 25 kDa, biologically active fragment of BPI. In this case, a vector can be generated comprising DNA residues 123 to about 759-780 (or **amino acid residues 1 to about 210-220**) of FIG. 5 using techniques well-known in the art.

(emphasis added). Applicants submit that the rejection of claim 14 for lack of written description may properly be withdrawn.

**Response To The Rejection of Claims 10-15  
For Obviousness-Type Double Patenting**

The Office Action dated March 25, 2005 rejected claims 10-15 under the judicially created doctrine of obviousness-type double patenting over claims 1-2 of U.S. Patent No. 5,641,874. Claims 11 and 15 were also rejected for obviousness-type double patenting over claim 3 of U.S. Patent No. 6,287,811. Claims 10-15 were also rejected for obviousness-type double patenting over claims 1-4, 6 and 7 of U.S. Patent No. 5,198,541.

In order to expedite the allowance and issuance of the present application, Applicants are submitting herewith a Terminal Disclaimer for the present application with respect to U.S. Patent No. 5,198,541, U.S. Patent No. 5,641,874 and U.S. Patent No. 6,287,811. Both the present application and U.S. Patent No. 5,198,541, U.S. Patent No. 5,641,874 and U.S. Patent No. 6,287,811 are assigned to New York University, as shown by the assignment attached to the Terminal Disclaimer.

Accordingly, the enclosed Terminal Disclaimer complies with 37 CFR 1.321 and is effective to overcome the obviousness-type double patenting rejections.

Applicants' submission does not constitute an admission as to the accuracy or effect of the obviousness-type double patenting rejections. The enclosed Terminal Disclaimer is submitted to expedite prosecution of the present application.

Please charge \$65.00 to Deposit Account No. 13-0017 to cover the fee (small entity) for submitting the Terminal Disclaimer.

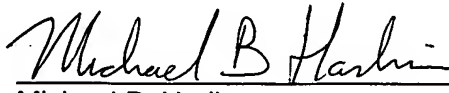
Applicants submit that the rejection of claims 10-15 for obviousness-type double patenting may properly be withdrawn.

### **Conclusion**

In view of the foregoing amendments and remarks, Applicants request allowance of claims 10-15. The Examiner is invited to telephone the undersigned to discuss any questions or be of any assistance to the Examiner in the reconsideration and allowance of this case.

Respectfully submitted,

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Michael B. Harlin  
Registration No. 43,658

McAndrews, Held & Malloy, Ltd.  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, Illinois 60661  
Telephone: (312) 775-8000  
Facsimile: (312) 775-8100